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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,913

05/19/2006

Hiroko Udagawa

Q94520

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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

06/23/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No.	Applicant(s)	
	10/579,913	UDAGAWA ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/21/09, 3/30/10, 6/4/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments and arguments filed Mar. 30, 2010 are acknowledged and have been fully considered. Claims 1-11 are cancelled; claims 12-15 are amended. Claims 12-15 are now pending and are now under consideration.

OBJECTIONS/REJECTIONS WITHDRAWN

The objection to the specification (i.e. the title) is withdrawn, in light of the amended title filed Mar. 30, 2010.

The rejection of claims 1-11 is moot in light of the claim cancellations.

The rejection of claims 12-15 under 35 U.S.C. 112, 2nd paragraph is withdrawn in light of the claim amendments.

OBJECTIONS/REJECTIONS MAINTAINED

The objection to the specification is maintained as discussed below.

The rejection of claims 12-15 under 35 U.S.C. 103(a) is maintained as discussed below.

Specification (Maintained)

The specification is objected to because the claim for domestic priority to PCT/JP04/17305 has not properly been made.

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It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/JP04/17305, filed 11/19/2004. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally

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delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that the instant application is a national stage application of PCT/JP04/17305, and cite to MPEP § 1893.03(c), arguing they are not required to claim the benefit of domestic priority on the first line of the specification (response, p. 8).

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The section of the MPEP cited by applicants refers to foreign priority, not the claim for domestic priority that was objected to in the prior Office Action. While applicants are entitled to the PCT international filing date, this date is not granted unless a proper claim is made. See MPEP § 201.11, 201.13(b), and 201.14. In particular, MPEP § 201.13(b) states, "As such, any later filed national application, or international application designating the United States, may claim the benefit of the filing date of an earlier international application designating the United States, if the requirements and conditions of section 120 of title 35 U.S.C. are fulfilled. A proper benefit claim has not yet been made.

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over BRACHT (WO 00/64418; Published Nov. 2, 2000) in view of NAKANO (U.S. 6,117,447; Issued Sep. 12, 2000; 1st Ref. on IDS dated 5/19/06) as evidenced by U.S. 6,689,379 (all references of record).

Since the WO document to Bracht is in German, U.S. 6,689,379, the national stage filing resulting from the international application, is relied upon herein as an English language equivalent. Column and line numbers refer to the '379 Patent.

1. Bracht discloses transdermal therapeutic patch systems that comprise pressure-sensitive adhesives and tulobuterol in an amount of 5% (title; abstract; col. 6, line 4; col. 7, lines 61-65; claims 1 and 2). Bracht teaches the use of 2-octyl dodecanol (i.e. elected species) in the transdermal preparations as a permeation enhancer in quantities from 10-80 % relative to the adhesive matrix (col. 6, lines 15-17; claim 10). Bracht teaches that polymers suitable for the formation of the pressure sensitive adhesive layer include polyacrylates constructed from both acrylic acid and methacrylic acid units or

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ester derivatives thereof (abstract; col. 1, lines 10-20; col. 2, line 59 to col. 3, line 3).

Bracht does not explicitly teach the instantly elected species of alkyl(meth)acrylate.

2. Nakano discloses percutaneous preparations comprising a support and an acrylic adhesive plaster layer laminated thereon which comprises tulobuterol in at least 5%. Nakano teaches that the acrylic adhesive comprises a copolymer comprising an alkyl(meth)acrylate having an alkyl group of up to 12 carbon atoms, the monomer in a proportion of not less than 50% (abstract; col. 2, lines 11-30). Nakano teaches the use of copolymers comprising 2-ethylhexyl(meth)acrylate and/or dodecyl(meth)acrylate (i.e. elected species) as a monomer in preferably not less than 60%, particularly in amounts of 60-98% (i.e. greater than 70%) (col. 3, lines 50-53; particularly col. 4, lines 6-11).

3. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use dodecyl(meth)acrylate as an esterified methacrylate monomer of Bracht's invention in amounts of greater than 70% as taught by Nakano. One would have been motivated to do so since Nakano teaches this very type of acrylate copolymer is a suitable choice for tulobuterol transdermal preparations. Further, both Bracht and Nakano are concerned with similar problems in the art, namely, the production of stable, transdermal delivery preparations for tulobuterol. Claims 12-15 are obvious over Bracht and Nakano.

Regarding the obviousness rejections herein, it is noted that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing

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discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that the references do not suggest a "copolymer obtained by copolymerization of monomers containing 2-ethylhexyl(meth)acrylate and an alkyl(meth)acrylate whose alkyl group is linear and has 6 to 20 carbon atoms (response, p. 10).

The examiner cannot agree. Nakano clearly teaches that suitable acrylic adhesives for the invention include polymers and copolymers obtained by polymerizing alkyl(meth)acrylates, including 2-ethylhexyl (meth)acrylate and dodecyl (meth)acrylate (col. 3, lines 40-50). Nakano teaches that the alkyl(meth)acrylate is preferably polymerized in a proportion of not less than 60%, thus, at least one of these monomers is preferably present in an amount not less than 60 wt. % (col. 3, lines 51-53). Selection of the specific monomers and their amounts is no more than routine optimization based on Nakano's disclosure. Moreover, Bracht teaches (meth)acrylate copolymers (col. 1, lines 11-14; col. 3, lines 43-45). Thus, in addition to Nakano's direct teachings, one

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would have a high expectation of success in copolymerizing the monomers taught by Nakano.

Furthermore, the MPEP states that the selection of known materials based on their suitability for their intended uses is *prima facie* obvious. See MPEP § 2144.07. “Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle.” 325 U.S. at 335, 65 USPQ at 301.).

It must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” *Id.* at 1742. No evidence of unexpected results has been presented or argued.

Consistent with this reasoning, it would have been obvious to have selected various combinations of the monomers directly taught by Nakano, to arrive at compositions “yielding no more than one would expect from such an arrangement”, in this case an adhesive capable of maintaining a high concentration of dissolved tulobuterol.

Applicants argue that Nakano teaches away from the claimed copolymer (response, p. 10).

Nakano does not teach away from the claimed copolymer because, as discussed above, this very copolymer falls within Nakano's teachings of what may be polymerized with the functional monomer. The two are distinct components as taught by Nakano.

NEW GROUNDS OF OBJECTION/REJECTION

Claim Objections

Claims 13-15 are objected to because either the changes to these claims were not indicated (claims 13 and 14) or the status identifiers are incorrect (claim 15). The changes in any amended claim must be shown by strike-through (for deleted matter) or underlining (for added matter) with some exceptions. If an amendment has been made to the claim, the changes should be indicated by these markings. See MPEP 714, subsection C. See also CFR 1.121. Appropriate correction is required.

Summary/Conclusion

Claims 12-15 are rejected; claims 1-11 are cancelled.

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Applicant's amendment necessitated the new ground(s) of objection/rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Kevin S Orwig/

/Sharmila Gollamudi Landau/
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